314.127 Refusal to approve an abbreviated new drug application.
314.150 Withdrawal of approval of an application or abbreviated application.
314.151 Withdrawal of approval of an abbreviated new drug application under section 505(j)(5) of the act.
314.152 Notice of withdrawal of approval of an application or abbreviated application for a new drug.
314.153 Suspension of approval of an abbreviated new drug application.
314.160 Approval of an application or abbreviated application for which approval was previously refused, suspended, or withdrawn.
314.161 Determination of reasons for voluntary withdrawal of a listed drug.
314.162 Removal of a drug product from the list.
314.170 Adulteration and misbranding of an approved drug.

Subpart E—Hearing Procedures for New Drugs

314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.
314.201 Procedure for hearings.
314.235 Judicial review.

Subpart F [Reserved]

Subpart G—Miscellaneous Provisions

314.410 Imports and exports of new drugs.
314.420 Drug master files.
314.430 Availability for public disclosure of data and information in an application or abbreviated application.
314.440 Addresses for applications and abbreviated applications.
314.445 Guidance documents.

Subpart H—Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses

314.500 Scope.
314.510 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.
314.520 Approval with restrictions to assure safe use.
314.530 Withdrawal procedures.
314.540 Postmarketing safety reporting.
314.550 Promotional materials.
314.560 Termination of requirements.

Subpart I—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

314.600 Scope.
314.610 Approval based on evidence of effectiveness from studies in animals.
314.620 Withdrawal procedures.
314.630 Postmarketing safety reporting.
314.640 Promotional materials.
314.650 Termination of requirements.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

SOURCE: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.

Subpart A—General Provisions

§ 314.1 Scope of this part.

(a) This part sets forth procedures and requirements for the submission to, and the review by, the Food and Drug Administration of applications and abbreviated applications to market a new drug under section 505 of the Federal Food, Drug, and Cosmetic Act, as well as amendments, supplements, and postmarketing reports to them.

(b) This part does not apply to drug products subject to licensing by FDA under the Public Health Service Act (58 Stat. 632 as amended (42 U.S.C. 201 *et seq.*)) and subchapter F of chapter I of title 21 of the Code of Federal Regulations.

(c) References in this part to regulations in the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[50 FR 7493, Feb. 22, 1985, as amended at 57 FR 17981, Apr. 28, 1992; 64 FR 401, Jan. 5, 1999]

§ 314.2 Purpose.

The purpose of this part is to establish an efficient and thorough drug review process in order to: (a) Facilitate the approval of drugs shown to be safe and effective; and (b) ensure the disapproval of drugs not shown to be safe and effective. These regulations are also intended to establish an effective system for FDA's surveillance of marketed drugs. These regulations shall be construed in light of these objectives.

§ 314.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this part.